

DEPARTMENT OF HEALTH

No. R. 501

30 April 2004

FOODSTUFFS, COSMETICS AND DISINFECTANTS ACT, 1972 (ACT 54 OF 1972)

REGULATIONS RELATING TO MARINE BIOTOXINS

The Minister of Health intends, in terms of section 15 (1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), to make regulations set out in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Directorate: Food Control), within three months of the date of publication of this notice.

SCHEDULE

Definitions

1. In these regulations **“the Act”** means the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), and any expression to which a meaning has been assigned in the Act shall bear that meaning and, unless context indicates otherwise-
“biotoxins” means harmful substances produced by certain marine algal species on which some shellfish feed;
“contaminant” means any substance which, though not added intentionally to food, is present in such food as a result of the production (including operations carried out in crop husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, transport, or holding of such food or as a result of environmental contamination, and does not include insect fragments, rodent hairs and other extraneous matter;
“shellfish” refers to all bivalve molluscs including pectinidae and marine gastropods but excluding octopus and squids.

General

2. For the purpose of section 2(1)(b) (i) of the Act, shellfish and shellfish products are hereby deemed to be contaminated, impure, or decayed if the following biotoxins exceed the corresponding limits when measured by the methods prescribed under the annexure to these regulations or any equivalent accredited method.

(a) Paralytic Shellfish Poisons	0.8 µg/g*
(b) Amnesic Shellfish Poisons	20 mg/g**
(c) Diarrhetic Shellfish Poisons	Below detection level

- *measured as saxitoxin equivalent per gram of edible shellfish flesh
- **measured as domoic acid concentration per gram edible flesh

ANNEXURE

Test methods for biotoxins in shellfish

3. The table shows recommended analytical test methods (column II) for the biotoxins in column I

Biotoxin	Test method
Paralytic shellfish poisons	Mouse bioassay according to AOAC 1990
Amnesic shellfish poisons	HPLC coupled to a UV detector for domoic acid according to AOAC, 1991
Diarrhetic shellfish poisons	LC coupled to MS detector Mouse bioassay according to AOAC

AOAC: Association of Official Analytical Chemists

HPLC: High Performance Liquid Chromatography

UV: Ultra-violet

LC: Liquid Chromatography

MS: Mass Spectroscopy